HEALTH CARE USE & POLICY STUDIES – Drug/Device/Diagnostic Use & Policy

PHP8
THE ASSOCIATION BETWEEN EUROPEAN MEDICINES AGENCY APPROVAL AND HEALTH TECHNOLOGY ASSESSMENT RECOMMENDATION

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OBJECTIVES: To find the association between duration of the process of marketing authorization (MA) approval at European Medicines Agency (EMA) and health technology assessment (HTA) recommendations in European Union (EU) countries. **METHODS:** EMA MA timing for new active substances (NASs) during 2007-2009 were analyzed based on publicly available information. HTA recommendations (positive, positive with restrictions, negative, not assessed) issued for the same medications in 6 EU countries (SMC, Scotland; AOTM Poland; CVZ, The Netherlands; HAS, France; NICE, UK; INFARMED, Portugal) were also analyzed based on public information. Hypothesizing that EMA approval process timing might be an indicator of complexity and potential issues in the dossier, the potential for longer EMA approval times being associated with less beneficial HTA recommendation was investigated. Analyses were performed per country as EMA decisions are centralized but HTA recommendations are taken independently by member states. **RESULTS:** A total of 86 NAS were approved by EMA in 2007-2009; mean time of approval was 460 days (median 423 days). In total, we expected 516 HTA recommendations (86 drugs assessed by 6 organizations). We found in total 138 positive, 77 positive with restrictions, 67 negative recommendations. 234 expected recommendations for 6 HTA included in this study were not assessed (45,3% of all expected recommendations). The association between HTA recommendation and approval time (in days) was analyzed using Spearman's rho rank correlation. There was statistically significant negative correlation between approval time and HTA recommendation in The Netherlands. More time needed for EMA approval was associated with less beneficial HTA recommendations. Correlations in other countries were not statistically significant. **CONCLUSIONS:** Our research indicates that a longer EMA approval process is associated with a less beneficial HTA recommendation in The Netherlands. Further research is required whether this indicates that the same issues that cause delays at EMA are reconsidered at HTA authorities.

PHP9
THE IMPACT OF INDICATION EXTENSIONS ON PHARMACEUTICAL PRICES

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OBJECTIVES: To assess the impact of an indication extension on pharmaceutical prices in 9 markets: Australia, Brazil, France, Germany, Italy, Japan, Spain, Turkey, and the UK. **METHODS:** Websites of the EMA and national regulatory agencies were surveyed to indentify medicines granted an indication extension between 2007 and 2013. Eight case studies (bevacizumab, trastuzumab, sunitinib, ivabradine, telmisartan, aripiprazole, paliperidone, and omalizumab) were selected based on market share and availability across the geographies of interest. The list prices, at ex-manufacturer levels, of these eight drugs and those of the medicines belonging to their therapeutic class (at ATC level 3) were collected for the period 2007-13. Price movements for these eight medicines were compared to the price evolution within their therapeutic class over the period. **RESULTS:** Based on the selected case studies, there is ambivalent synchrony between indication extensions and pharmaceutical list price movements in the countries analysed. The data show that list prices tend to remain stable following an indication extension. When list prices changed subsequent to an indication extension, the movements could not directly be linked to the indication extension, as external factors such as a class trend or a wider pricing and reimbursement process (e.g. blanket price cuts) could also play a role. **CONCLUSIONS:** There is inconclusive evidence that indication extensions lead to list price changes in the countries analysed. Moreover, the impact of commercial agreements and discounts should be taken into account as secondary indications may be subject to separate pricing arrangements (e.g., patient access schemes). As such, the selection of the indication for the first marketing-authorisation filing (such as a high medical need, niche indication, commanding a premium price) is pivotal for the commercial success of a medicine, as its launch price seems unlikely to be reviewed following subsequent approvals in broader patient populations.

PHP10
ECONOMIC ANALYSIS OF THE PREVENTION OF MEDICAL SHARPS INJURIES WITH SAFETY-ENGINEERED DEVICES: A SYSTEMATIC REVIEW

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OBJECTIVES: To protect health care workers from risk of needlestick injury, preventive safety measures are increasingly mandated in the health care environment, which may include the use of safety-engineered medical sharp devices (SEDs) specifically designed to prevent sharps injuries. We undertook a systematic review of the literature to understand the economic impact of replacing conventional sharps devices with SEDs. **METHODS:** We conducted searches of electronic databases including Embase/MEDLINE, PubMed, CINAHL Plus, HEED, NHS EED, the Cochrane Library, ProQuest Nursing and Allied Health Source, and the Tufts CEA Registry. Databases of the WHO and HTA agencies, reference lists of identified studies, conference abstract books and the internet were also searched. The time horizon covered January 1990 to March 2013. Two reviewers independently screened titles and abstracts, applied inclusion criteria to full text papers and extracted data from identified studies according to an a priori defined data set. Differences were resolved by consensus. Study quality was assessed using a published 10-point checklist. **RESULTS:** From 19621 records, 21 studies met the review criteria and were selected. Most studies (16) were budget impact analyses (BIAs). Reductions in sharps injuries with SEDs ranging from 12% to 100% were reported. Just 4 studies were assessed as providing the best quality evidence: a cost benefit analysis and 3 BIAs. Key assessment criteria that the other studies did not meet were consideration of all relevant costs and execution of a sensitivity analysis. Of the best quality studies, 3 reported net economic benefits from implementing SEDs, at least in the base case analysis. **CONCLUSIONS:** Investment in SEDs generates economic benefits from savings in managing medical sharps injuries and their sequelae. Future economic evaluations need to carefully assess all important and pertinent costs to enable well-informed decision making about the implementation of SEDs in the health care workplace.

PHP12
A PRICE COMPARISON STUDY OF RECENT DRUGS IN EU5, 2008-2012

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OBJECTIVES: To compare prices of new drugs between France and the other EU4. **METHODS:** Study used IMS MIDAS database for economic data such as prices and sales volume and LEEM database (French association of the pharmaceutical manufacturers) for the ASMR scale (HAS assessment of the drug's added value/innovation). All the products applying for the first time for reimbursement by the French Public health insurance between January 2008 and June 2012 were included in the study (except those restricted to hospital use in France) and having an ASMR rating and an official price in June 2012. Paasche and Laspeyres price-index were calculated for drugs with: a) high ASMR, b) ASMR IV, c) ASMR V and d) all drugs. A sensitivity analysis was conducted to measure the effect of different weighting options. **RESULTS:** A total of 107 products (245 dosages) were included in this study. Fifty-one (48%) have been found available in the community pharmacies of all the 5 countries. The availability analysis by pair of countries (France + another) is higher: 94 for Germany, 79 for UK, 71 for Spain and 69 for Italy (Italy often restricts drug's access to hospitals only). French prices are generally equal to or lower than prices in the four other markets, which shows a relative price index decrease for France since 2008 studies. The only significant exception are UK prices for products ranked in France ASMR 1-2-3 (20% less expensive). Prices are regularly and significantly higher in Germany than in all other countries. Interestingly, the highest disparities in prices occur for the ones ranked as most innovative in France – while ASMR IV have surprisingly consistent prices across EU5. **CONCLUSIONS:** European patients don't have consistent access to the same drugs in retail market, and the drugs considered innovative in France show a large price index disparity across EU5, with UK prices being 20% lower.

PHP13
TO WHAT EXTENT CAN BIOSIMILARS COMPETE WITH BRAND NAME BIOLOGICS? A EU-5 GRANULOCYTE-COLONY STIMULATING FACTORS MARKETS ANALYSIS

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OBJECTIVES: To determine the ability of biosimilars (copies of branded biologics) to compete with brand name biologics within the same therapeutic class by analyzing EU-5 G-CSF (Granulocyte-Colony Stimulating Factors) markets and the factors affecting the G-CSF biosimilar uptakes, particularly that of biosimilar prices relative to reference G-CSFs. **METHODS:** Data on medicine volumes, values and ex-manufacturer prices for all G-CSF categories were provided by IMS Health. Volumes were calculated in DDD (Defined Daily Doses) and prices in euros per DDD. In the EU-5 countries biosimilar G-CSFs benefit from a 5-year experience. Data were available from 2007 until 2011. **RESULTS:** There are two G-CSF market profiles: i) countries with a high retail market distribution which are the largest G-CSF markets with low global G-CSF biosimilar uptakes (5.4% in France and 8.5% in Germany in 2011); ii) countries with a dominant hospital channel which are the smallest markets with higher G-CSF biosimilar uptakes (12.4% in Spain and 20.4% in the UK). The G-CSF biosimilar uptakes depend critically on their market access at a local/regional level. The more the decisions are decentralized (hospitals, local purchasing structures) the more their uptakes are high (28.3% of the hospital market in France in 2011 and 20.4% in the UK). The price difference between G-CSF biosimilars and their reference plays a marginal role at a global level (+13.3% in the UK and -20.4% in France). **CONCLUSIONS:** The competition with G-CSF biosimilars varies significantly between EU-5 countries due to distribution channel differences. Currently, this competition is not mainly based on prices, but on local political options to stimulate tendering between them and other most recently branded products. In countries with dominant retail markets, a prerequisite for the success of biosimilar G-CSFs is that governments approve their substitution in the same way generics are authorized by introducing them case-by-case.

PHP14
CHARACTERISING PRELIMINARY PROFILE PARAMATERS FOR FDA BREAKTHROUGH THERAPY CANDIDATES

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OBJECTIVES: Since the new Breakthrough Therapy (BT) designation was introduced with the new Food and Drug Administration Safety and Innovation Act (FDASIA) on 9 July 2012, the FDA has received over 50 requests, and has issued over 20 such designations to various candidates in various indications based on preliminary evidence that the investigational drugs fulfill a highly unmet medical need where no alternatives exist, or demonstrate a significant improvement over existing therapies. We have set out to examine the key parameters that characterise a "Breakthrough" candidate, and to determine the likelihood of an investigational therapy being granted the status. **METHODS:** Using the FDA listing of BT designation statistics, publicly available information, as well as IHS Global Insight data, we identified a list of currently approved BT candidates between 9 July 2012 and 14 June 2013 and determined their preliminary profile characteristics. **RESULTS:** To date, nearly 75% of the designations have been publicly announced by the pharmaceuticals firms